



12/17/04

17u

Express Mail No. EV 456 932 746 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Albone *et al.*

Confirmation No.: 9476

Application No.: 10/687,035

Group Art Unit: 1632

Filed: October 15, 2003

Examiner: To be Assigned

For: ANTIBODIES THAT BIND CELL-
ASSOCIATED CA 125/0772P AND
METHODS OF USE THEREOF

Attorney Docket No.: 6750-214-999

THIRD INFORMATION DISCLOSURE STATEMENTCommissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application. This paper is being filed pursuant to C.F.R. § 1.34.

1. Enclosures accompanying this Information Disclosure Statement are:

1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.

1b. A legible copy of:

☒ Each U.S. patent application publication and U.S. and foreign patent;☒ Each publication or that portion which caused it to be listed on the PTO-1449;☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;☐ all other information or portion which caused it to be listed on the PTO-1449.1c. ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

- ☒ Before the mailing of the first Office action on the merits;
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114 (filed herewith).

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed
- ☐ to be charged to Jones Day Deposit Account No. 50-3013.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Jones Day Deposit Account No. 50-3013.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
6. ☐ This application is a continuation application under 37 C.F.R. §1.60 or §1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)


- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently

filed herewith.

- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application, and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- (Check Item 8a, 8b, or 8c)
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 50-3013.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

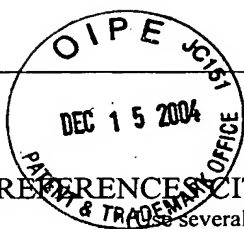
Respectfully submitted,

Date: December 15, 2004



Roger C. Rich
Nikolaos C. George, Reg. 39, 201
JONES DAY
222 East 41st Street
New York, New York 10017-6702
(212) 326-3939

54,398
(Reg. No.)



LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY DOCKET NO.

6750-214-999

APPLICATION NO

10/687,035

APPLICANT

Albone *et al.*

FILING DATE

October 15, 2003

GROUP

To be assigned

U.S. PATENT DOCUMENTS

| *EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|----------------------|-----|-----------------|--------|----------------------|-------|----------|-------------------------------|
| | C01 | 2003-0104442 A1 | 6/5/03 | Lloyd, <i>et al.</i> | | | |
| | C02 | 2004-0127401 A1 | 7/1/04 | O'Brien | | | |

FOREIGN PATENT DOCUMENTS

| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | |
|--|-----|-----------------|----------|---------|-------|----------|-------------|----|
| | | | | | | | YES | NO |
| | C03 | EP 1256354 | 11/13/02 | EPO | | | | |
| | C04 | WO02007783 | 1/31/02 | PCT | | | | |
| | C05 | WO02083866 | 10/24/02 | PCT | | | | |
| | C06 | WO02092836 | 11/21/02 | PCT | | | | |
| | C07 | WO04045553 | 6/3/04 | PCT | | | | |
| | C08 | WO03076473 | 9/18/03 | PCT | | | | |
| | C09 | WO03076465 | 9/18/03 | PCT | | | | |

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|-----|---|
| C10 | Beck, <i>et al.</i> (1994) "In Vitro Activity of Immunoconjugates Between Cisplatin and an Anti-CA125 Monoclonal Antibody on Ovarian Cancer Cell Lines", <i>Cell Biophysics</i> , 24/25: 163-173. |
| C11 | Beck, <i>et al.</i> (1998) "CA 125 Production and Release By Ovarian Cancer Cells In Vitro", <i>Int. J. Biol. Markers</i> , 13(4): 200-206 163-173. |
| C12 | Byrd, <i>et al.</i> (2004) "Mucins and Mucin Binding Proteins in Colorectal Cancer", <i>Cancer and Metastasis Reviews</i> , 23(1/2): 77-99. |
| C13 | Candido, <i>et al.</i> (2003) "CA 125 and Vascular Endothelial Growth Factor in the Differential Diagnosis of Epithelial Ovarian Tumors", <i>Gynecologic and Obstetric Investigation</i> , 54(3): 132-136. |
| C14 | Chang, <i>et al.</i> (2002) "Assessment of Plasma DNA Levels, Allelic Imbalance, and CA 125 as Diagnostic Tests for Cancer", <i>Journal of the National Cancer Institute</i> , 94(22): 1697-1703. |
| C15 | Davis, <i>et al.</i> (1986) "Characterization of the CA125 Antigen Associated With Human Epithelial Ovarian Carcinomas", <i>Cancer Research</i> , 46(12 Pt 1): 6143-6148. |
| C16 | Evans, <i>et al.</i> (2003) "Oregovomab", <i>American Journal of Cancer(Auckland, New Zealand)</i> , 2(2): 125-133. |
| C17 | Fendrick, <i>et al.</i> (1997) "CA125 Phosphorylation Is Associated With Its Secretion From the WISH Human Amnion Cell Line", <i>Tumor Biology</i> , 18: 278-289. |
| C18 | Guppy, <i>et al.</i> (2002) "CA125 Response: Can It Replace the Traditional Response Criteria in Ovarian Cancer", <i>The Oncologist</i> , 7: 437-443. |
| C19 | Hu, <i>et al.</i> (2003) "Expression of Mucins and Cytokeratins In Ovarian Cancer Cell Lines", <i>Current Opinion in Molecular Therapeutics</i> , 5(6): 625-630. |
| C20 | Imbert-Marcille, <i>et al.</i> (1994) "Modulation of Associated Ovarian Carcinoma Antigens by 5 Cytokines Used As Single Agents Or In Combination", <i>Int. J. Cancer</i> , 57: 392-398. |
| C21 | Kabawat, <i>et al.</i> (1983) "Immunopathologic Characterization of a Monoclonal Antibody That Recognizes Common Surface Antigens of Human Ovarian Tumors of Serous, Endometrioid, and Clear Cell Types", <i>Am J. Clin. Pathol.</i> , 79(1): 98-104. |
| C22 | Lamerz, Rolf. (1998) "34.4 CA 125", <i>Gastrointestinal Cancer Antigens</i> , 34.4: 969-972. |
| C23 | Lloyd, <i>et al.</i> (1997) "Isolation and Characterization of Ovarian Cancer Antigen CA 125 Using a New Monoclonal Antibody (VK-8): Identification As A Mucin-Type Molecule", <i>Int. J. Cancer</i> , 71: 842-850. |
| C24 | Lloyd, <i>et al.</i> (2001) "Synthesis and Secretion of the Ovarian Cancer Antigen CA 125 by the Human Cancer Cell Line NIH:OVCAR-3", <i>Tumor Biology</i> , 22: 77-82. |

| | |
|-----|---|
| C25 | Manetta, <i>et al.</i> (1989) "Therapeutic Effects of A Radiolabeled Monoclonal Antibody on Human Ovarian Cancer Xenograft in Nude Mice", <i>Gynecologic Oncology</i> , 32: 368-370. |
| C26 | Marth, <i>et al.</i> (1998) "Regulation of the CA 125 Expression in Cultured Human Carcinoma Cells", <i>The Int. J. of Biol. Markers</i> , 13(4): 207-209. |
| C27 | Maughan, <i>et al.</i> (1990) "OC125 Immunoscintigraphy In Ovarian Carcinoma: A Comparison With Alternative Methods of Assessment", <i>Clinical Oncology</i> , 2: 199-205. |
| C28 | McQuarrie, <i>et al.</i> , (1997) "Pharmacokinetics and Radiation Dosimetry of ^{99m} Tc-Labelled Monoclonal Antibody B43.13 In Ovarian Cancer Patients", <i>Nuclear Medicine Communications</i> , 18: 878-886. |
| C29 | McQuarrie, S.A. (1998) "The Effects of Circulating Antigen on the Pharmacokinetics and Radioimmunoscintigraphic Properties of ^{99m} Tc Labelled Monoclonal Antibodies in cancer Patients", <i>Journal Pharm. Pharmaceut. Sci.</i> , 1(3): 115-125. |
| C30 | Molthoff, <i>et al.</i> (1991) "Human Ovarian Cancer Xenografts In Nude Mice: Characterization and Analysis of Antigen Expression", <i>Int. J. Cancer</i> , 47: 72-79. |
| C31 | Nap, <i>et al.</i> (1998) "Immunohistochemistry of CA 125 Unusual Expression in Normal Tissues, Distribution in the Human Fetus and Questions Around Its Application In Diagnostic Pathology", <i>The International Journal of Biological Markers</i> , 13(4): 210-215. |
| C32 | Nakai, <i>et al.</i> (1993) "Changes in CA125 Release and Surface Expression Caused by Drugs in Uterine Cervix Adenocarcinoma Cells", <i>Annals of Nuclear Medicine</i> , 7(3): 133-139. |
| C33 | Nustad, <i>et al.</i> (1998) "CA 125 - Epitopes and Molecular Size", <i>The Int. J. of Biol. Markers</i> , 13(4): 196-199. |
| C34 | O'Brien, <i>et al.</i> (1998) "More Than 15 Years of the CA 125: What is Known About the Antigen, Its Structure and Its Function", <i>The Int. J. of Biol. Markers</i> , 13(4): 188-195. |
| C35 | Prinssen, <i>et al.</i> (1998) "Biodistribution of ¹¹¹ In-Labelled Engineered Human Antibody CTM01 (HCTM01) In Ovarian Cancer Patients: Influence of Prior Administration of Unlabelled HCTM01", <i>Cancer Immunol. Immunother.</i> , 47: 39-46. |
| C36 | Reinartz, <i>et al.</i> (2004) "Vaccination of Patients with Advanced Ovarian Carcinoma with the Anti-Idiotypic ACA125: Immunological Response and Survival (Phase Ib/II)", <i>Clinical Cancer Res.</i> , 10: 1580-1587. |
| C37 | Reinartz, <i>et al.</i> (2003) "Interleukin-6 Fused to an Anti-Idiotypic Antibody in a Vaccine Increases the Specific Humoral Immune Response Against CA125 (MUC-16) Ovarian Cancer", <i>Cancer Res.</i> , 63: 3234-3240. |
| C38 | Reinsberg, <i>et al.</i> (1999) "Falsely Low Results in CA 125 Determination Due to Anti-Idiotypic Antibodies Induced by Infusion of [¹³¹ I]F(ab') ₂ Fragments of the OC125 Antibody", <i>Eur. J. Clin. Chem. Clin. Biochem</i> , 31: 323-327. |
| C39 | Rump, <i>et al.</i> (2004) "Binding of Ovarian Cancer Antigen CA125/MUC16 to Mesothelin Mediates Cell Adhesion", <i>The Journal of Biol. Chem.</i> , 279(10): 9190-9198. |
| C40 | Sakahara, <i>et al.</i> (1996) "Effect of Circulating Antigen on Immunoscintigraphy of Ovarian Cancer Patients Using Anti-CA 125 Monoclonal Antibody", <i>Jpn. J. Cancer Research</i> , 87: 655-661. |
| C41 | Schneider-Gadicke, <i>et al.</i> (1992) "Analysis of Cytotoxicity of ¹³¹ I-Labelled OC125 F(ab') ₂ on Human Epithelial Ovarian Cancer Cell Lines", <i>Radiotherapy and Oncology</i> , 23: 150-159. |
| C42 | Schorge, <i>et al.</i> (2004) "Osteopontin as an Adjunct to CA125 in Detecting Recurrent Ovarian Cancer", <i>Clinical Cancer Research</i> , 10(10): 3474-3478. |
| C43 | Schultes, <i>et al.</i> (2003) "Monitoring of Immune Responses to CA125 with an IFN-gamma ELISPOT assay", <i>Journal of Immunological Methods</i> , 279(1,2): 1-15. |
| C44 | Sjovall, <i>et al.</i> (2002) "The Significance of Serum CA 125 Elevation in Malignant and Nonmalignant Diseases", <i>Gynecologic Oncology</i> , 85: 175-178. |
| C45 | Stimpfl, <i>et al.</i> (1999) "Expression of Mucins and Cytokeratins In Ovarian Cancer Cell Lines", <i>Cancer Letters</i> , 145: 133-141. |
| C46 | Sweet, <i>et al.</i> (1989) "Daunorubicin Conjugated to a Monoclonal Anti-CA125 Antibody Selectively Kills Human Ovarian Cancer Cells", <i>Gynecologic Oncology</i> , 34: 305-311. |
| C47 | Verheijen, <i>et al.</i> (1999) "CA 125: Fundamental and Clinical Aspects", <i>Seminars In Cancer Biology</i> , 9: 117-124. |
| C48 | Yin, <i>et al.</i> (2001) "Molecular Cloning of the CA125 Ovarian Cancer Antigen: Identification As A New Mucin (MUC16)", <i>American Society for Biochemistry and Molecular Biology, Manuscript (MI 103554200)</i> 1-28. |
| C49 | Yin, <i>et al.</i> (2002) "Ovarian Cancer Antigen CA125 is Encoded by the MUC16 Mucin Gene", <i>Int. J. Cancer</i> , 98(5): 737-740. |

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.